DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2939523

July 11, 2000

Richard L. Lawson, President
Products Carousel Inc.
1728 Sanger Avenue
Sanger, CA 93657

WARNING LETTER

Dear Mr. Lawson:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1728 Sanger Avenue, Sanger, CA 93657 on May 15 and 16, 2000. During the inspection, Investigator Thomas W. Gordon collected samples of Choo-Hooves, All Natural Dog Chewies, and Choo-Hooves Pressed Sticks for FDA laboratory analyses. FDA laboratory analyses revealed that the Choo-Hooves Pressed Sticks are contaminated with *Salmonella*, a pathogenic bacteria. The Choo-Hooves Pressed Sticks are, therefore, adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). The introduction or delivery for introduction into interstate commerce of an adulterated food is prohibited under Section 301(a) of the Act.

It is your responsibility as the manufacturer of pet foods to assure that your products are safe, wholesome, and not contaminated with pathogenic bacteria. At the conclusion of the inspection, Investigator Gordon made several recommendations to improve your manufacturing process. One of the recommendations is to segregate raw materials from finished products to eliminate the potential for cross contamination. We emphasize the importance of this recommendation. We also recommend that you review the current Good Manufacturing Practices, codified in Title 21, Code of Federal Regulations, Part 110. See attached for how to obtain FDA regulations.

You should take prompt action to correct the violation and prevent future recurrences. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Darrell T. Lee
Acting District Director

Enclosure